December 17, 2020

pjur group Luxembourg SA
% Candace Cederman
Consultant
Candace F. Cederman
722 Arjean Drive
Wilmington, NC 28411

Re: K200730
Trade/Device Name: pjur® med SENSITIVE glide, pjur® WOMAN Nude
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 14, 2020
Received: November 17, 2020

Dear Candace Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200730

Device Name
pjur® med SENSITIVE glide, pjur® WOMAN Nude

Indications for Use *(Describe)*

pjur® med SENSITIVE glide for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® WOMAN Nude for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
K200730

DATE PREPARED:	16 December 2020
APPLICANT:	pjur group Luxembourg SA 87 esplanade de la Moselle L-6637 Wasserbillig, Luxembourg Telephone: +352 74-8989 Fax: +352 74-8990
CONTACT:	Andrea Giebel, Quality Management Representative
TRADE NAME:	• pjur® med SENSITIVE glide • pjur® WOMAN Nude
COMMON NAME:	Personal Lubricant
REGULATION NUMBER:	21 CFR §884.5300
REGULATION NAME:	Condom
PRODUCT CODE:	NUC (Lubricant, Personal)
DEVICE CLASS:	2
PREDICATE DEVICE:	KY Grosz Jelly, K201186 The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:

The pjur® med SENSITIVE glide and pjur® WOMAN Nude are water-based personal lubricants provided non-sterile. These over-the-counter products have an identical formulation and contain neither a contraceptive nor a spermicide. They are compatible with natural rubber latex condoms and are not compatible with polyurethane or polyisoprene condoms. The pjur® med SENSITIVE glide is provided in 100 mL polyethylene bottles and the pjur® WOMAN Nude is provided in either 10 mL or 100 mL polyethylene bottles.

The pjur® med SENSITIVE glide and pjur® WOMAN Nude consists of water, 1,2 propylene glycol, ethyoxydiglycol, hydroxypropyl guar hydroxypropyltrimonium chloride, hydroxyethylcellulose, sodium saccharin, and citric acid.

Table 1: Device Specifications

Parameter	Method	Specification
Appearance		Clear fluid
Odor		Odorless
pH	USP<791>	4.0-4.5
Viscosity (mPa*s)	USP<912>	4000-5600
Osmolality (mOsmol/kg)	USP <785>	500-700 mOsm/kg [diluted 1:9.6)

Parameter	Method	Specification	
Total Yeast and Mold Count (TYMC)	USP<61>	<10 CFU/g	
Total Aerobic Microbial Count (TAMC)	USP<61>	<100 CFU/g	
Presence of pathogenic organisms	USP<62>	*Pseudomonas aeruginosa*	Absent
		Staphylococcus aureus	Absent
		Candida albicans	Absent
Antimicrobial Preservation	USP<51>	Category 2 - Topical, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days.	

INDICATIONS FOR USE:

pjur® med SENSITIVE glide for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® WOMAN Nude for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

SUMMARY OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE IN COMPARISON TO THE PREDICATE DEVICE:

Table 2: Comparison of Intended Use and technological characteristics of the subject and predicate devices:

	pjur® med SENSITIVE glide/pjur® WOMAN Nude K200730 Subject Device	**KY Grosz Jelly K201186 Predicate Device**	**Comparison**
Indications for Use	pjur® med SENSITIVE glide for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms. pjur® WOMAN Nude for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.	This product is intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	**Same intended use**
Rx / OTC	OTC	OTC	**Same**
Base Type	Water	Water	**Same**
Primary Ingredients	Purified water 1,2 propylene glycol Ethyoxydiglycol Hydroxypropyl guar hydroxypropyltrimonium chloride Hydroxyethylcellulose Sodium Saccharin Citric Acid	Water Propylene glycol Hydroxyethylcellulose Benzoic acid Carbomer Sodium hydroxide	**Different**
Appearance	Clear liquid	Clear and translucent jelly	**Different**
Odor	Odorless	No objectionable odor	**Different**
Viscosity	4000-5600 mPa*S	40,000-100,000 cPs	**Different**
pH	4.0-4.5	3.5-4.5	**Similar**
Osmolality	500-700 mOsm/kg [diluted 1:9.6)	780-1180 mOsm/kg	**Different**
Microbial Limits	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	**Same**
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Yes	Yes	**Same**
Sterile	No	No	**Same**
Biocompatibility Tested	Yes	Yes	**Same**

	pjur® med SENSITIVE glide/pjur® WOMAN Nude K200730 Subject Device	**KY Grosz Jelly K201186 Predicate Device**	**Comparison**
Condom Compatibility	Compatible with natural rubber latex condoms. Not compatible with polyurethane and polyisoprene condoms	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms	**Different**
Packaging	Polyethylene bottles	Polyethylene bottle and foils	**Different**
Shelf Life	4 years	1.5 years	**Different**

The subject and predicate device indications for use are not identical due to differences in condom compatibility; however, they have the same intended use (i.e., provide lubrication during intimate sexual activity).

The subject devices and the predicate device have different technological characteristics, including different formulations, specifications, shelf-life, packaging, etc. as identified in the table above. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

NON-CLINICAL TESTING/PERFORMANCE DATA:

CONDOM COMPATIBILITY:

Condom compatibility testing was performed in accordance with ASTM D7661-10 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.” Testing demonstrated that the subject devices are compatible with natural rubber latex condoms and are not compatible with polyurethane and polyisoprene condoms.

BIOCOMPATIBILITY:

Biocompatibility studies were performed in accordance with the 2016 FDA guidance document “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process” as follows:

- Cytotoxicity: ISO 10993-5:2009
- Sensitization: ISO 10993-10:2010
- Vaginal Irritation: ISO 10993-10:2010
- Systemic Toxicity: ISO 10993-11:2017

The results of the testing show that the formulation of the subject devices is biocompatible.

SHELF-LIFE:

The pjur® med SENSITIVE glide and pjur® WOMAN Nude lubricants have a shelf-life of four years in accordance with the results of a real-time stability study. Results from testing demonstrated that the device can maintain its specifications as shown in Table 1 over the duration of its shelf-life.

CONCLUSION:

The results of the performance testing demonstrate that the pjur® med SENSITIVE glide and pjur® WOMAN Nude personal lubricants are as safe and effective as the predicate and support a substantial equivalence determination.